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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,129	12/26/2001	Rajneesh Taneja	ABB1259P0072US (6762.US.0	3432

7590 12/30/2003

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,129	TANEJA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (3 months) and the Amendment, both filed 09/22/03 is acknowledged.

The 35 U.S.C. §112 second paragraph rejections and the 35 U.S.C. § 102(b) rejections of Phillip I ('737) have been *withdrawn.*

Claims 1-29 are pending. Claims 1, 13, 15 and 26 have been amended. Claims 1-29 remain rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-11, 15-21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Phillips (US Pat. No. 6,489,346 B1).

Phillips ('346) discloses a method for treating acid-related gastrointestinal disorders comprising administering to a patient a non-enteric pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent, wherein the pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and wherein the composition also discloses a carbonate salt of a Group IA metal (see Abstract, claims and col. 11, line 13 through col. 14, line 25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 12-14, 22 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pat. No. 5,840,737, hereafter '737) in view of Phillips (US Pat. No. 6,489,346 B1, hereafter '346).

Phillips ('737) teaches a method for treating gastric acid disorders by administering to a patient a single dose of a pharmaceutical composition including an aqueous solution/suspension of proton pump inhibitors – omeprazole, lansoprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims). Phillips also teaches a pharmaceutical composition, which includes omeprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims).

Phillips teaches a method for treating gastric acid disorders wherein the Group IA metal is sodium and potassium (see claims 1-3).

It is stated that the pharmaceutical composition is prepared by mixing omeprazole or other substituted benzimadoles and derivatives thereof with a solution including a bicarbonate salt of a Group IA metal. Preferably, omeprazole powder or granules are mixed with a sodium bicarbonate solution to achieve a desired final omeprazole concentration (col. 7, line 50 through col. 8, line 5).

Phillip states that the pharmaceutically acceptable carrier includes the bicarbonate salt of the Group IA metal and can be prepared by mixing the bicarbonate salt of the Group IA metal, which is preferably sodium bicarbonate, with water. The

concentration of the bicarbonate salt of the Group IA metal in the composition generally ranges from approximately 5.0% to about 60%. In a preferred embodiment, the preferred salt is sodium bicarbonate and is contained in a concentration of about 8.4% (col. 8, lines 6-17).

Suitable derivatives of omeprazole can be substituted for the omeprazole or other suitable substituted benzimidazoles, wherein these derivatives include lansoprazole (col. 8, lines 41-45).

The pharmaceutical composition can be used for the treatment of gastrointestinal conditions, including, active duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), severe erosive esophagitis, poorly responsive systematic GERD, and pathological hypersecretory conditions (col. 8, lines 46-61).

The examples on columns 10-19 further demonstrate various embodiments of the invention in greater detail.

Additional agents that can be added include antimicrobial preservatives, antioxidants, chelating agents and buffers (column 9, lines 23-26).

Phillips is deficient in the sense that he does not explicitly teach the instant ratios. However, in the absence of showing the criticality of the instantly claimed ratios and/or amounts, it is deemed obvious to one of ordinary skill in the art that suitable ratios and/or amounts could be determined through routine or manipulative experimentation.

The instant claims recite a method for treating gastric acid disorders comprising a non-enteric coated proton pump inhibitor. Phillips teaches a method for treating gastric acid disorders whereby the use of enteric coatings can be used if desired. It is obvious

to one of ordinary skill in the art to either include or exclude enteric coatings based on the administration form desired.

Phillips ('737) does not teach carbonate salt of the Group IA metal.

Phillips '346 teaches a method for treating acid-related gastrointestinal disorders comprising a non-enteric coated proton pump inhibitor composition comprising at least one buffering agent, wherein suitable buffering agents include *sodium carbonate* (see abstract and column 13, line 63 – column 14, line 13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Phillips ('346) within the teachings of Phillips ('737) because Phillips ('346) explicitly teaches a method for treating acid-related gastrointestinal disorders comprising a formulation with non-enteric coated proton pump inhibitors in combination with suitable buffering agents, such as sodium carbonate and similarly Phillips ('737) teaches a method for treating gastric acid disorders whereby the composition comprises various proton pump inhibiting compounds in combination with additional agents that include buffering agents. The expected result would be a non-enteric coated formulation for the effective treatment and/or prevention of gastric acid related disorders, as similarly desired by the applicant.

Response to Arguments

Applicant's arguments filed 09/22/03 have been fully considered but they are not persuasive on all grounds. The applicant argued regarding the 35 U.S.C. §102(b) rejections of claims 1-7, 9, 15-21 and 23 over Phillips I and the 35 U.S.C. §102(b) rejections of claims 1-7, 9-11, 15-21, 23 and 24 over Phillips II and the 35 U.S.C. §103(a) rejection of claims 8, 10-14, 22 and 24-29 stating,

"Phillips I and II each disclose the use of bicarbonate salts and do not disclose the use of carbonate salts in the formulations set forth therein. They do not disclose the use of both carbonate and bicarbonate salts as required by the present claims. Thus, neither Phillips I nor Phillips II anticipates any of claims 1-29."

"With respect to the Section 103(a) rejection, neither Phillips I nor Phillips II disclose or suggest the use of both carbonate and bicarbonate salts as is presently claimed. Thus, there is no motivation for a skilled artisan to obtain the subject matter of claims 1-29 and the Section 103(a) rejection should be withdrawn."

These arguments have been thoroughly considered and were found to be persuasive in terms of the 35 U.S.C. 102(b) anticipation rejection of Phillips '737 only. Accordingly, that anticipation rejection has been withdrawn. However, the 35 U.S.C. 102(e) rejection of Phillips '346 has been maintained.

The prior art (Phillips II or '346) discloses compositions and methods for treating gastric acid disorders by the administration of a pharmaceutical composition comprising non-enterically coated proton pump inhibitors (i.e., omeprazole, lansoprazole, other substituted benzimidazoles) and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises bicarbonate salts and carbonate salts of a Group

IA metal (see abstract and claims). The pharmaceutical composition can be used for the treatment of gastrointestinal conditions, including, active duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), severe erosive esophagitis, poorly responsive systematic GERD, and pathological hypersecretory conditions (col. 8, lines 46-61). Phillips ('346) teaches various buffering agents that include sodium bicarbonate, potassium bicarbonate and sodium *carbonate*, for example (see ref. col. 13, line 63 – col. 14, line 13). Phillips ('737) is lacking only in the sense that he does not teach the carbonate salts of the Group IA metal from the Periodic Table of Elements. However, he does teach that additional agents, such as buffering agents may be incorporated. Furthermore, Phillips ('346) remedies this only deficiency of Phillips ('737) by teaching the incorporation of at least one buffering agent; wherein buffering agents include sodium carbonate as instantly claimed. Therefore a *prima facie* case of obviousness has been established since the prior art provides ample motivation to incorporate the same ingredients for treating gastric acid disorders. Moreover, the applicants have not shown or demonstrated any unexpected results that accrue from the use of components contained in their instant invention. The prior art teaches a similar formulation comprising the same ingredients for the same field of endeavor, which is the treatment and/or prevention of gastric acid related disorders. Hence, the instant invention remains anticipated, obvious and unpatentable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
December 17, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600